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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,971	09/28/2001	Dale R. Schulze	14826 (ETH-1579)	5810

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Scully, Scott, Murphy, & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER

ROBERTS, PAUL A

ART UNIT PAPER NUMBER

3731

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,971

Applicant(s)

SCHULZE, DALE R.

Examiner

Paul A Roberts

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J.W.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 2,5,6,9-13,15,17-20,22-26,28-33,35 and 37-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7,8,14,16,21,27,34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed January 8, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the Whitehill et al. reference likely has the wrong document number. No copies of this patent or WO 98/37218 were submitted. Additionally, WO 98/37218 is likely not the intended reference, since the patent subject matter is not analogous the applicant's claims. It assumed from the submitted references that the intended references are US 3,019,789 and WO 99/37218. These references have been considered by the examiner.

Election/Restrictions

2. Claim 6 does not read on the elected invention because it does not describe an end-to-side anastomosis procedure. Claims pending are 1, 3, 4, 7, 8, 14, 16, 21, 27, 34, and 36. Claims 2, 5-6, 9-13, 15, 17-20, 22-26, 28-33, 35, and 37-40 are withdrawn from further consideration.

Claim Objections

3. Claim 21 is objected to because of the following informalities: line 13 of page 27 claims 'for causing said wire...' this fragment is missing a word or two. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 (and thus all claims dependent on claim 1) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is not clear what the 'means [for] implementing anastomosis' or 'means for causing said wire' are. Please refer directly to specification to state the element that is synonymous with the two 'means'. Also, the 'means implementing anastomosis' is missing the word 'for'.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 34 recites the limitation "said suture wire" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3, 7, 8, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Vargas et al. "Vargas" US 6,478,804.
7. Regarding claim 1, Vargas discloses an arrangement comprising a wire (116, fig 20) inherently capable of having one end inserted into a target vessel by puncturing the wall of said vessel and exiting said vessel by puncturing the wall at a spaced location so as to define a region of contact between said vessels, said wiring being inherently capable of puncturing through said walls of said graft vessel upon position of said graft vessel on target vessel. Element 14d, of fig 24 is a means for implanting anastomosis, and element 110 is a means for causing said wire to through the adjoining walls. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
8. Regarding claim 3, the Vargas wire is longitudinally reciprocated. The definition from the specification of longitudinal reciprocated requires the wire to be a cheese cutter. The Vargas wire is inherently capable of cutting cheese.
9. Regarding claim 7, figure 19 shows an end-to-side anastomosis formation.
10. Regarding claim 8, said wire extends towards the interior of said graft vessel and exits through opposite side walls thereof at a spacing from said target vessel, said wire being movable so as to align and contact said vessels with each other (figures 19 and 20).
11. Regarding claim 16, the step of stitching sutures about the joining sides of the vessel (figure 33).

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12. Claims 21, 27, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by LeMole US 5,893,369. LeMole discloses an anastomosis system and method comprising: a method for implementing a vascular anastomosis between a graft vessel and a target vessel and subsequently creating a fluid flow passageway between said vessels; said method comprising: inserting a wire (24, figure 6) with one end into said target vessel by puncturing the wall of said vessel (22) and exiting said vessel by puncturing the wall at a spaced location so as to define a region of contact between said vessels (space between both ends of 24); said wire puncturing through the walls of said graft vessel (12) upon positioning of said graft vessel on said target vessel; implementing anastomosis between said vessels in said region of contact between said vessels (the anastomosis is implemented with the region, but just not exclusively within that region); and for causing said wire to cut through the adjoining walls of said vessels within the confines of said region of contact (since the puncturing locations define the region, the wire inherently stays within that region) so as to create said fluid flow passageway between said vessels. The wires are stitched to cause the suture to join the sides of the vessels to abut the graft vessel to the target vessel.

13. Claims 1 & 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Northrup III et al "Northrup" US 5,972,024. Northrup discloses an apparatus for anastomosis as well as a method of using his device. In figure 8, Northrup shows the method of joining two vessels. A wire (20) is disclosed. The wire is capable of puncturing the wall of the vessels. A hook-shaped needle is disclosed. The needle is dimensioned to define the distance between the inserting and exiting punctures in the walls.

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Allowable Subject Matter

No prior art rejection is made for claim 4 or claim 34.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5486187 A Schenck, Robert R. Anastomosis device and method

US 20010018592 A1 Schaller, Laurent et al. Bridge clip tissue connector
apparatus and methods

EP 314412 A1 Silvestrini, Thomas A Device for tendon and ligament
repair.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
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20/10/03


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